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Subject: Environmental Defense comments on Phosphonic acid, methyl-, dimethyl ester (CAS# 756-79-6)

(Submitted via Internet 7/14/04 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, lucierg@msn.com and william.gentit@akzonobel-chemicals.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for Phosphonic acid, methyl-, dimethyl ester (CAS# 756-79-6)

The test plan and robust summaries for Phosphonic acid, methyl-, dimethyl ester, also called dimethyl methylphosphonate (DMMP), were submitted by the DMMP consortium, which apparently consists of Akzo Nobel Functional Chemicals and Rhodia Inc. According to the test plan, DMMP is manufactured in a closed system and is used to produce downstream products, including ones produced by other manufacturers. DMMP applications include flame retardants, hydraulic fluids, antifoam agents, plasticizers and textile conditioners.

The sponsor states that there is limited opportunity for exposure from these applications, but no data are provided to substantiate this claim. We recommend that the sponsor make available any environmental monitoring data and also indicate concentrations of residual DMMP in its many applications. This information is especially important from an environmental and public health perspective for chemicals such as DMMP, which have a broad array of applications.

The sponsor contends that existing data are adequate to meet HPV requirements for SIDS endpoints with two exceptions -- toxicity to aquatic invertebrates and algae -- and studies are proposed to address those data gaps. We agree that studies on the two aquatic toxicology endpoints are needed, but we have some concerns over the adequacy of the data provided for some of the other endpoints. In particular we are concerned about the environmental fate endpoints and reproductive toxicity.

Regarding the environmental fate endpoints, we note that the biodegradation data are comprised of a study which monitors activated sludge respiration and reports an EC50 value of > 10g/l. What do these data mean for the biodegradation of DMMP and are such data sufficient to meet HPV requirements? Also, are phosphates released as biodegradation products? The test plan indicates that fugacity and photodegradation data were estimated using EPA models. However, no data are provided from these models in the robust summaries so we cannot evaluate their adequacy at this time.

The information presented in the test plan and robust summaries is confusing. The sponsor states that the reproductive toxicity endpoint is met by histologic data obtained from two repeat dose studies, one conducted by industry and the other by the NTP. While the data on male reproductive toxicity is sufficient, the same cannot be said for female reproductive

toxicity. The industry repeat dose study, according to the robust summaries, was compromised by the presence of SDA infections in experimental animals (both males and females). The NTP studies were from a two-year cancer bioassay and there was apparently no interim sacrifice. Histological data from reproductively senescent animals cannot be reliably used to assess reproductive toxicity. NTP did conduct a reproductive toxicity study in males which indicated that the male reproductive tract is a target organ for DMMP, including effects on fertility, degenerative lesions and positive results for dominant lethal mutations, but no corresponding studies were conducted in females. Therefore, we find that the female reproductive toxicity endpoint is not met and hence such a study needs to be conducted.

Other points that need to be addressed in a revised submission are as follows:

1. The robust summaries indicate a variety of test substances were used to conduct studies on SIDS endpoints. Some of the listed substances are Fryol DMMP, MCTR 196-77, MCTR 129-78, and VGC 89549, as well as DMMP itself. What are the purities of each of these substances, and are there impurities and/or additives in them that could influence the test results?

2. DMMP appears to be negative in the Ames test but positive in some tests for chromosomal aberrations, mutation frequency in cultured cells and mammalian cell transformation. Why are the data negative for the Ames tests and positive for the other tests?

Thank you for this opportunity to comment.

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